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TITLE: Evaluation of a Brief Marriage Intervention for Internal Behavioral Health Consultants in Primary Care

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14. ABSTRACT At the conclusion of the second year we have enrolled 251 participants (126 couples) into the study. The majority (87%) assigned to the treatment condition have completed all three appointments. Attrition rates at the one-month and six-month follow-up points are low (5% to 10%). Total enrollment continues to run behind projected enrollment goals (70%). An IRB audit of study documentation from 2016 identified errors in a significant number of enrollment documents. While the errors were judged to be not-serious noncompliance, the IRB board voted that all participants with errors must be re-consented or data not used. We are aggressively pursuing re-consents and having success but some loss of data is likely.					
15. SUBJECT TERMS Military personnel, marital relations, couple therapy, primary care					
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Evaluation of a Brief Marriage Intervention for Internal Behavioral Health Consultants
in Military Primary Care
Year 1 Annual Report

Introduction

The most challenging community problems faced by senior military leaders are closely linked to the quality of marriage relationships. These include family violence, spouse maltreatment, and suicide. Despite the potential high costs of chronic marital distress, very few couples seek therapy. Thus, there is a substantial need in the military for early detection and preventative care for deteriorating couples. The Marriage Checkup (MC) addresses this issue by providing a less-threatening option for couples to seek early preventative care before they have begun to identify as distressed. In our pilot study the original MC was adapted for military couples and fit into the fast-paced environment of primary care. The results of the pilot study provide preliminary evidence suggesting that the MC can be effectively adapted to a military population, and successfully used by behavioral health consultants (BHCs) working in an integrated primary care clinic. The overall purpose of the current study is to build on the pilot study findings by conducting a randomized trial of the military-adapted MC delivered in primary care by BHCs. Specific Aims of the study are (1) conduct a randomized trial comparing MC for use in military primary care clinics to a wait list control condition, (2) examine the effects of MC participation on relationship health at post-treatment and a six-month follow-up period, and (3) determine whether the MC is successful at reaching couples at risk for marital deterioration who would otherwise be unlikely to seek traditional couple counseling. The randomized trial is being conducted at three military primary care clinics at Lackland, Andrews, and Luke Air Force Bases.

Keywords

Military personnel, marital relations, couple therapy, primary care

Accomplishments

1. What were the major goals of the project?

	Timeline	
	Months	% complete
Major Task 1: Complete all preparatory work for project start.		
Subtask 1: Complete Research Protocol and Regulatory Documents		
Finalize baseline and follow-up measures; prepare data recording forms	1-3	100%
Establish process for participant incentive payments	1-3	100%
Refine eligibility criteria, exclusion criteria, screening protocol	1-3	100%
Finalize consent form & human subjects protocol	1-3	100%
Finalize methods for participant recruitment	3-6	100%
Purchase, establish use of IPADS for facilitating on-line baseline assessments	3-6	100%
Coordinate with Sites for flow chart for all study steps, web data collection and database requirements	3-6	100%
Coordinate with Sites for IRB protocol submission	1-6	100%
Coordinate with Sites for State University IRB review	1-6	100%

Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO)	1-6	100%
Submit IRB amendments as needed	1-6	100%
Coordinate with Sites for annual IRB report for continuing review	1-6	100%
<i>Milestone Achieved: Local IRB approval at all research sites and Universities</i>	3	100%
<i>Milestone Achieved: HRPO approval for all protocols and local IRB approval through State Univ.</i>	6	100%
Subtask 2: Hiring and Training of Study Staff		
Coordinate with WSU Human Resources for job description design	1-2	100%
Advertise, interview and hire site-specific study coordinators	2-5	100%
Coordinate for space allocation for new staff at data collection sites	5-6	100%
Coordinate military base access for study coordinators	5-6	100%
Travel to sites to train IBHCs and study coordinators	7-9	100%
<i>Milestone Achieved: Study coordinators hired</i>	6	100%
<i>Milestone Achieved: IBHCs and study coordinators trained</i>	9 (Actual date: 6/23/16)	100%
<i>Milestone Achieved: All sites 100% ready for beginning RCT</i>	9 (Actual date: 6/23/16)	100%
Major Task 2: Begin RCT; Participant recruitment, intervention, assessment		
Conduct participant recruitment, baseline and 1-month follow-up assessments	10-15	100%
Conduct random assignment to MC or wait list stratified by site	10-15	100%
Ensure process for securing documents w/ personal identifiers in PI's office	10-15	100%
Conduct website data transfer, data quality checks, data base management	10-15	100%
Conduct weekly clinical supervision with IBHCs	10-15	100%
Conduct weekly supervision with study coordinators	10-15	100%
Submit amendments, adverse events and protocol deviations as needed	10-15	100%
Perform data analyses; share output and finding with all investigators	14-15	100%
Meet recruitment targets (3 couples per site per mo. /total 144 all sites per 12 mo.)	10-15	100%
<i>Milestone Achieved: RCT began successfully; 1st participant consented, enrolled</i>	10 (Actual Date: 2/16/2016)	100%
Major Task 3: Continue RCT; Begin 6 mo. f/u assessments		

Continue participant recruitment, baseline and 1-month follow-up assessments	16-21	100%
Continue random assignment to MC or wait list stratified by site	16-21	100%
Continue weekly clinical supervision with IBHC's	16-21	100%
Continue weekly supervision with study coordinators	16-21	100%
Continue website data transfer, data quality check, data base management	16-21	100%
Meet recruitment targets (3 couples per site per mo./total 144 all sites per 12 mo.)	16-21	70% as of 1 Sep
Submit amendments, adverse events and protocol deviations as needed	16-21	100%
Begin 6 mo. Follow-up assessments	16	100%
Begin offering MC to participants in wait list condition	16	100%
Perform data analyses; share output and findings with all investigators	20-21	0%

2. What was accomplished under these goals?

Protocol-level accomplishments:

- a. Processes and documentation required for participant consenting, administering and management of baselines measures, providing incentive payments, and obtaining and managing follow-up measures IAW IRB-approved protocol are all established and functioning effectively.
- b. The team holds a weekly teleconference every Friday at 11:00 AM EST. The first Friday of the month is the all team call, second Friday is Andrews AFB, the third Friday is Luke AFB, and the fourth Friday is Lackland AFB. An additional teleconference for the Research Assistants occurs weekly on Wednesday afternoon at 4:00 PM EST. A third teleconference to provide clinical supervision to the therapists is held every other week on Monday at 9:00 EST.
- c. An all team in person meeting was held in San Antonio on February 27 – March 1. At this meeting the team participated in a Marriage Checkup training refresher conducted by Dr. James Cordova, discussed logistics of the project, and developed a weekly recruitment strategy that is currently implemented by all bases.
- d. Study progress was presented at the Ft Detrick IPR in April 2017. The IPR panel asked that we increase the number of therapists on the protocol at each site to help mitigate the effects of provider PCS and job-change. We have attempted to follow-through with this recommendation.
- e. A total of 251 participants (126 couples) have been consented into the study and randomized to conditions as of 9/1/2017. The majority (87%) of couples assigned to the treatment condition have completed all three appointments and several recently enrolled are still pending completion (see attached CONSORT chart).

- f. Participant attrition (lost to follow-up) from the study has been low and equally distributed across treatment and control conditions. As of 1 September, attrition at the one-month follow-up is 9.5% for treatment participants and 9.2% for control participants. Similarly, attrition at six months is currently 5.0% for treatment and 10.6% for control (see attached CONSORT chart).

Site-Specific Accomplishments:

Randolph AFB & Lackland AFB, Texas.

- a. Dr. Jennifer Mitchell left her position at Randolph AFB in November 2016. Since Dr. Mitchell's departure, there has not been a replacement therapist added to the protocol at Randolph. Advertisement for the study is posted at Randolph with interested couples enrolled at Lackland AFB site.
- b. Dr. Dawn Kessler-Walker was added to the protocol as a therapist at Lackland AFB. IRB approved of Dr. Kessler-Walker was obtained on 23 January 2017. We now have two therapists at Lackland AFB.
- c. Research Assistant, Rosalyn Pace, left her position 15 July 2017. A new RA, Virginia Cruse, accepted the position on 28 July 2017 and was approved by the IRB to interact with participants on 19 September 2017.
- d. Current total couple enrollment at Lackland AFB as of 1 September: 40
- e. Current total couple enrollment at Randolph AFB as of 1 September: 8

Andrews AFB, Maryland.

- a. A new therapist was added to the study, Capt Andrea Weiss. Capt Weiss was approved by the IRB to engage in research on 3 May 2017. Capt Weiss will serve as the local PI at Andrews AFB, replacing Lt Col Vanecek.
- b. A second therapist, Capt Ashley Kilgore, was added to the protocol and approved by the IRB on 19 September 2017. We now have two therapists at Andrews AFB.
- c. Current total couple enrollment at Andrews AFB as of 1 September 17: 28

Luke AFB, Arizona.

- a. Aroosa Barech was hired as a Research Assistant replacing Gary Delago. Ms. Barech was approved by the IRB to engage in research on 23 January 2017.
- b. Our therapist at Luke AFB, Dr. John Gassaway left his position and the research study in July 2017. We have recruited a replacement therapist, Dr. Angela Kenzlowe, but there has been a delay in getting required IRB documentation signed by her contract agency supervisor. Due to the non-responsiveness of her contract supervisor, the IRB chair on 21 September approved a work-around of having her military supervisor sign. That documentation is still pending.
- c. Current total couple enrollment at Luke AFB as of 1 September 17: 50

Wright-Patterson AFB, Ohio

- a. We obtained IRB approval to add W-P as a data collection site on 14 February 2017. HRPO approval was received on 6 July 2017. Unfortunately, our local PI and therapist at W-P, Maj Michael Ann Glotfelter, deployed for six months beginning in July. There are two contract psychologists in primary care at W-P. In August we educated them about the study and they both expressed an interest in participating. Currently they are working on educating their chain of command about the study. Although the study is approved for W-P, the Commander has changed out since the original approval. We are hoping to be able to move forward with W-P in October but the pattern so far has been delays.

3. What opportunities for training and professional development has the project provided?

This project provided initial certification training to conduct Marriage Checkup for Primary Care to nine Internal Behavioral Health Consultants (IBHCs) at four medical treatment facilities in the Air Force. The project also provides ongoing clinical supervision to the nine IBHC. These nine psychologists are quickly becoming the most experienced therapists in the world for implementation of a brief relationship intervention in the primary care setting. Their growing expertise will serve as the foundation in the future for effective dissemination and implementation of Marriage Checkup for primary care in the DoD.

4. How were the results disseminated to communities of interest? N/A

5. What do you plan to do during the next reporting period to accomplish the goals?

- a. New couple recruitment has lagged over the summer (see changes/problems section below). Our immediate action beginning in October will be to reinvigorate our recruitment efforts.
- b. We now have two therapists on the protocol at both Lackland and Andrews AFBs. This should help maintain availability of therapy appointments to see couples.
- c. Our highest performing site, Luke AFB, has not had a therapist for several months. I am hopeful we can get the second therapist added to the study within the next several weeks. Then we are poised to ramp back up recruitment at Luke
- d. I will continue to do everything I can to get the Wright-Patterson AFB site up and running.

6. Impact

1. What was the impact on the development of the principal discipline(s) of the project?

The principle disciplinary field of the project is behavioral health services in an integrated primary care context. Our experience on the project over the past two years has convinced us that brief relationship assistance can be effectively incorporated into primary care. Our primary care therapists have consistently reported that they enjoy conducting Marriage Checkup and that it is a positive experience for the couples who participate.

2. What was the impact on other disciplines?

The primary care clinic teams at our four data collection sites now have an in-house resource for referring patients who are interested in and may benefit from brief consultation for improving their marital relationship.

3. What was the impact on technology transfer? Nothing to report

4. What was the impact on society beyond science and technology? Nothing to report

Changes/Problems

1. In May 2017 the Air Force IRB conducted a routine audit of study documentation from 2016 and reported the findings on 25 July 2017. The auditor found two types of documentation errors:
 - a. Errors on the Informed Consent Document (ICD). The majority of the errors were that signature dates for the participant differed from the dates for the investigator and witness signature. This occurred as a result of the witness (the RA) and Investigator (local PI) delaying signing the ICD for several days or week following the consenting. Though consented properly, the signatures did not occur on the same date. A minority of the errors occurred when the RA conducted the consenting away from the medical treatment facility (which was approved by the IRB) but failed to obtain a witness signature.
 - b. Missing HIPAA documents. On 20 May 2016 a protocol amendment was submitted to the IRB to add Luke AFB and other new personnel to the study. An amended HIPAA was mistakenly not submitted with the other (numerous) amendment documents. The IRB approved the amendment on 10 July 2016 and provided the new documents for use in the study, i.e., protocol, ICD, but did not catch the fact that a HIPAA was not submitted. We forwarded the newly approved documents out to our RAs for use in consenting participants and again failed to notice that a HIPAA was not included. Our RAs (mostly at Lackland site) began using the new documents without obtaining a signed HIPAA form from participants. This went on for about two months before we realized that participants were not completing a HIPAA form. We alerted the IRB and submitted an updated HIPAA for approval. The IRB asked that we contact previously consented participants and obtain a signed HIPAA form. At the time of the study audit we were still lacking signed HIPAAs for some participants.

2. The IRB directed that the study discontinue enrolling participants until the audit findings were addressed by the study PIs.
3. The Air Force PI (Capt Fields) and overall study PI (Dr. Cigrang) prepared a written report regarding the audit findings and attended the 22 Aug 2017 IRB board meeting. We made an appeal that errors in dates on the ICDs did not represent improper consenting and the original ICDs be considered sufficient. We also appealed for a similar judgment on the missing HIPAAs because no information from or about participants was obtained from their medical record.
4. A notice of action dated 29 August was received from the IRB board stating the following:
 - a. The Board voted to **approve** the issue as **not serious** noncompliance. No change to the current approval period was made. Participant enrollment could resume.
 - b. The IRB also voted to **disallow** the use of any research data that was obtained from research subjects who were improperly consented to the study or did not provide proper HIPAA Authorization.
5. HRPO was notified of the audit concerns and the IRB board outcome on 21 August 2017.
6. The study team has been actively working on re-consenting study participants. Below is a summary of progress.
 - a. Luke AFB.
 - i. 36 participants with errors in documentation
 - ii. 13 participants have been reconsented.
 - b. Andrews AFB
 - i. 21 participants with errors in documentation
 - ii. 12 participants have been reconsented.
 - c. Lackland AFB
 - i. 30 participants with errors in documentation.
 - ii. We've not had an RA at Lackland since July. New RA recently approved by IRB and is now working on the re-consents
 - d. Electronic signature for ICD and HIPAA. We submitted a protocol amendment for use of e-signatures for participant who have moved out of local area. IRB approval was obtained on 22 September 2017.
7. **Products** Nothing to report

Participants & Other Collaborating Organization

Name	Project Role	Nearest person month worked	Contribution to Project	Funding Support
Dr. Jeffrey A. Cigrang	PI	6	Served as the Principal Investigator for the Marriage Checkup (MC) project. Led effort to prepare, submit, & obtain final IRB approval. Worked with WSU Human Resources to complete all tasks necessary to post positions and hire research assistants. Oversaw work done by subcontract team at Clark University. Coordinated all aspects of study with Air Force.	NA
Dr. James Cordova	Co-PI	6	Primary responsibility for clinical supervision of study therapists. Oversaw all aspects of study at Clark University. Participated in weekly team teleconferences that include providing clinical supervision to therapists on MC.	U.S. Department of Health and Human Services
Capt. Abby Fields	Co-PI	6	Served as Air Force PI for IRB purposes. Served as therapist seeing couples enrolled in study at Wilford Hall Medical Center. Helped supervise Research Assistant (Rosalyn Pace). Participated in weekly team teleconferences.	NA
Capt. Michael Ann Glotfelter	AI	6	Served as therapist seeing couples enrolled in study at Wilford Hall Medical	NA

			Center. Helped supervise RA (Rosalyn Pace). Participated in weekly team teleconferences.	
Maj Elizabeth Najera	AI	6	Responsible for behavioral health integration in primary care for Air Force. Continues to provide guidance in weekly team teleconferences for implementing MC in primary care.	NA
Maj Jolyn Tatum	AI	6	Served as local PI at Andrews AFB until August 2016. Oriented new RA hired at her site. Participated in weekly teleconference.	NA
Lt Col Jodi Vanecek	AI	6	Served as local PI at Andrews AFB beginning August 2016. Serving as therapist seeing couples enrolled at Andrews AFB.	NA
Dr. Jennifer Mitchell	AI	6	Served as therapist seeing couples enrolled in study at Randolph AFB clinic. Helped supervise RA (Rosalyn Pace).	NA
Rosalyn Pace	Research Assistant	12	Served as RA for both Randolph and Lackland AFB sites in San Antonio. Helped development and implement participant recruitment plan. Served as primary POC for study in San Antonio. Scheduled, consented, completed baseline assessments for all participants.	NA
Rosalind DiYanni	Research Assistant	6	Served as RA for Andrews AFB. Helped development and implement participant recruitment plan. Served	NA

			as primary POC for study at Andrews AFB. Scheduled, consented, completed baseline assessments for all participants.	
Gary Delago	Research Assistant	6	Served as RA for Luke AFB. Helped development and implement participant recruitment plan. Served as primary POC for study at Andrews AFB. Scheduled, consented, completed baseline assessments for all participants.	NA
Tatiana Gray	Graduate Student	6	Primary team member responsible for use of on-line follow-up surveys. Monitors implementation, downloads de-identified results, converts to database for statistical analyses. Continues to assist Dr. Cordova on creation of the MC website and preparation of materials for training MC therapists. Prepared minutes from MC weekly teleconferences. Helped work out all logistics for conducting participant consenting, baseline assessment, randomization.	NA
Ashley Evans	Graduate Student	6	Had primary responsibility for revisions to IRB and other regulatory documents. Prepared drafts of quarterly reports. Took lead in orienting new RAs to study, assisted in completion of their IRB requirements. Scheduled	NA

			team teleconferences. Prepared documents required for HRPO submission. Led weekly teleconference for RAs	
Emily Maher	Graduate Student		Took over duties from Tatiana Gray at the end of September 2016. Primary team member responsible for use of on-line follow-up surveys. Monitors implementation, downloads de-identified results, converts to database for statistical analyses. Prepared minutes from MC weekly teleconferences. Assisted Ashley in conducting weekly teleconferences for the Research Assistants.	NA
Aroosa Barech	Research Assistant		In January 2017, Aru took over duties as the Research Assistant at Luke AFB from Gary Delago. Helped development and implement participant recruitment plan. Served as primary POC for study at Andrews AFB. Scheduled, consented, completed baseline assessments for all participants.	NA
Dr. Dawn-Kessler Walker	AI		Served as therapist seeing couples enrolled in study at Wilford Hall Medical Center starting in January 2017. Helped supervise RA (Rosalyn Pace). Participated in weekly team teleconferences.	NA
Dr. John Gassaway	AI		Served as local PI at Luke AFB beginning March 2016. Serving as therapist	NA

			seeing couples enrolled at Luke AFB. Helped supervise RA (Gary Delago and currently Aroosa Barech).	
Capt Andrea Weiss	AI		Served as local PI at Andrews AFB beginning May 2017. Serving as therapist seeing couples enrolled at Andrews AFB. Helped supervise RA (Rauz DiYanni).	NA
Virginia Cruse	Research Assistant		In September 2017, Virginia took over duties as the Research Assistant at Lackland AFB and Randolph AFB from Rosalyn Pace. Virginia will help with re-consenting of participants at Lackland and Randolph and implement a participant recruitment plan. Virginia will serve as primary POC for the study at Lackland and Randolph AFB. She will manage scheduling, consenting, and completion of baseline assessments for all participants.	NA
Capt Ashley Kilgore	AI		Capt Kilgore will serve as a therapist seeing couples in the study at Andrews AFB starting in September of 2017. Capt Kilgore has assisted with the supervision of the local RA (Rauz DiYanni) and participated in weekly team teleconferences.	

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

No changes

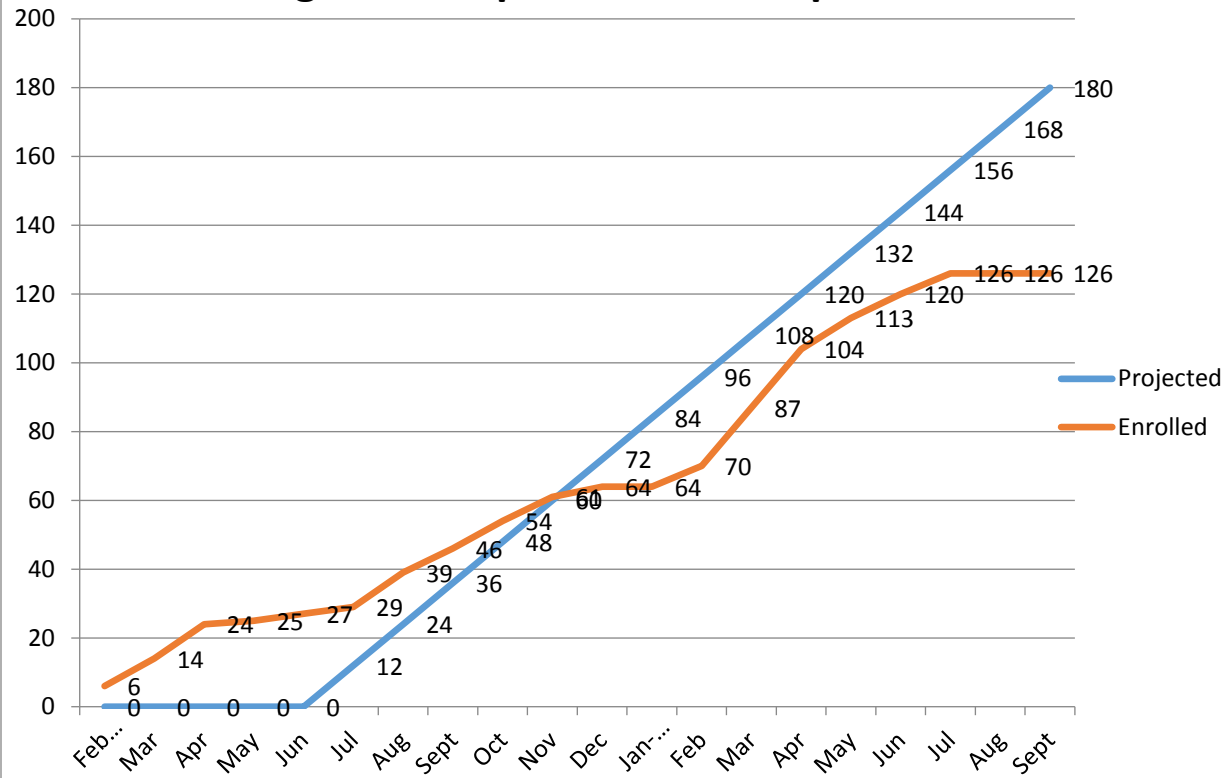
Special Reporting Requirements

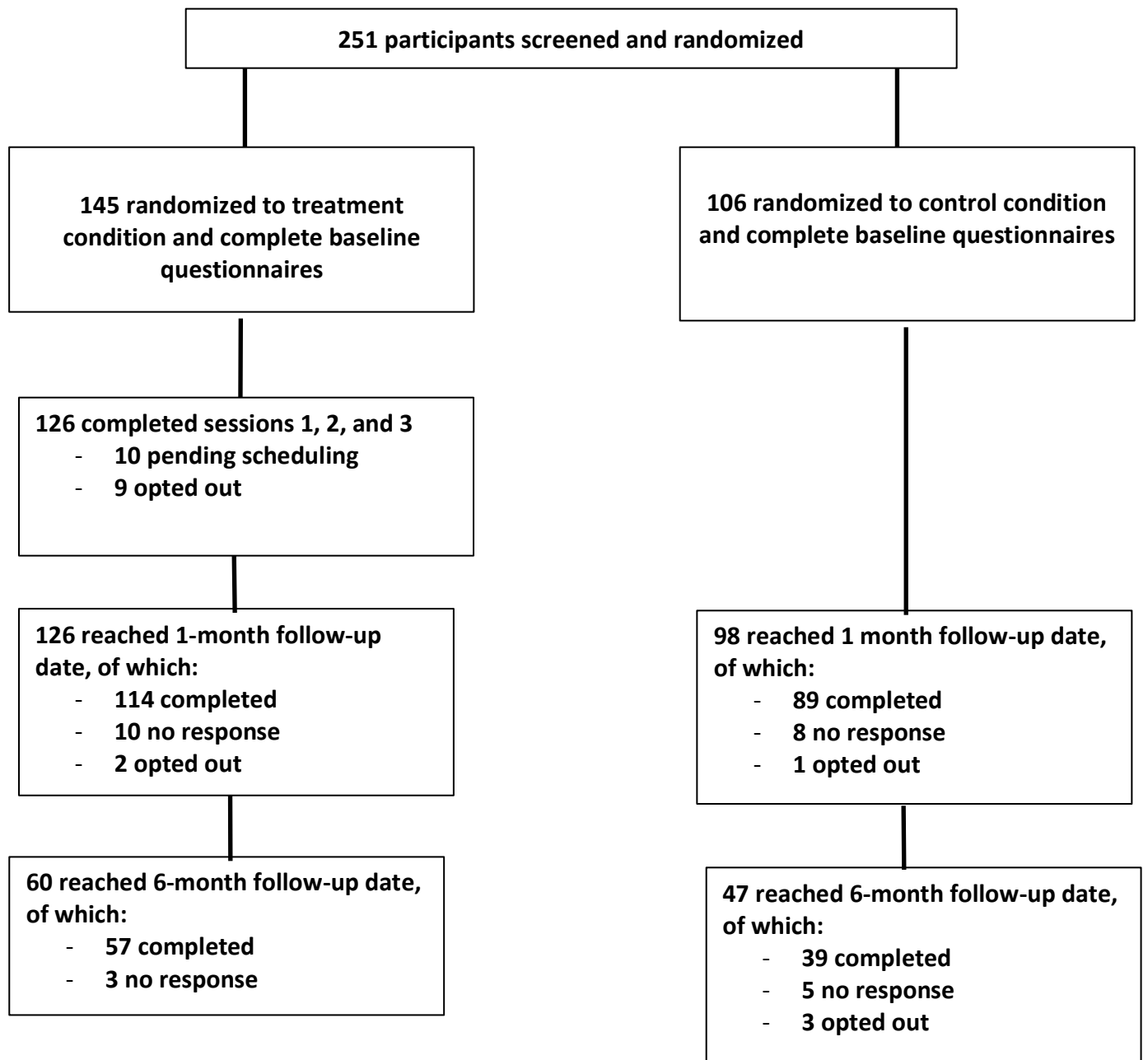
See attached quad chart

Appendices

- a. Participant Enrollment: Actual versus Projected.
- b. COHORT chart
- c. Quad Chart

Marriage Checkup Enrollment September 2017





Evaluation of a Brief Marriage Intervention for Internal Behavioral Health Consultants in Primary Care

Log #14227006, W81XWH-15-2-0025

PI: Jeffrey A. Cigrang, Ph.D., ABPP

Org: Wright State University

Award Amount: \$878,979



Study/Product Aim(s)

- Recruit service members and their partners who are in committed romantic relationships to participate in a Marriage Checkup (MC) delivered by Integrated Behavioral Health Consultants (IBHC) in primary care.
- Evaluate the efficacy of MC by comparing couples who receive MC to couples on a wait list control condition.
- Determine the ability of MC to attract military couples across a broad range of relationship functioning.
- Obtain qualitative data from IBHCs and couples after conclusion of the intervention study portion to measure MC implementation and factors impacting success.

Approach

Conduct a randomized clinical trial (N=250 couples) at four primary care clinics in the Air Force to evaluate effects of MC participation.



Accomplishments: (1.) Enrolled 251 participants (126 couples). (2) The majority (87%) assigned to treatment condition have completed all three appointments. (3) Attrition rates at the one-month and six-month follow-up points are low (5% to 10%).

Timeline and Cost

Activities	CY	15	16	17	18
Preparatory work for project start					
Begin RCT; meet recruitment targets					
Continue RCT; report 6 mo. f/u results					
Complete RCT and qualitative data collection					
Estimated Budget (\$878,979)		\$20,300	\$350,000	\$350,000	\$158,679

Goals/Milestones

CY15 Goal – Complete preparatory work for project start

- ✓ Obtain IRB approval at all sites and Universities
- ✓ Hire site-specific study coordinators.

CY16 Goals – Begin RCT

- ✓ Obtain HRPO approval
- ✓ Complete training for study coordinators and therapists.
- ✓ Begin participant consenting; meet recruitment targets

CY17 Goal – Continue RCT

- ✓ Continue participant consenting; meet recruitment targets.

CY18 Goal – Complete RCT and qualitative data collection

- ☐ Report findings from 6 mo. f/u assessments and qualitative interviews, focus groups

Budget Expenditure to Date

Projected Expenditure: \$878,979.00

Actual Expenditure: \$476,768.993 Through 8-31-2017